

Appendix 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Satoko YAMAHIRA, et al.

Serial No.: 10/568,671

Art Unit: 1651

Filed: February 17, 2006

Examiner: Irene MARX

For: LACTIC ACID BACTERIA CAPABLE OF STIMULATING MUCOSAL
IMMUNITY

DECLARATION UNDER 37 C.F.R. § 1.132

Honorable Commissioner of Patents and Trademarks

Washington, D.C. 20231

SIR:

I, Satoko YAMAHIRA declare that:

- 1) I am one of the inventors of the above-identified application and am familiar with the subject matter of said application as well as the disclosures in the cited references.
- 2) In order to demonstrate the advantages of the present invention, the following experiments were carried out under my direction and supervision.

Experimental Report

Method

Lactobacillus plantarum ONC141 was obtained, and, using IgA S.I., IgA production of the strain was compared. The IgA concentration in culture supernatant was measured in accordance with the method described in the present specification, page 39, line 16 to page 40, line 7 of the English specification.

Results

A measured value of the culture supernatant obtained by adding 10 µl of PBS(-) to an MEM medium (no bacteria added) and performing a culture for seven days was defined as the standard (1.0), and the relative ratios (Stimulation Index: S.I.) were calculated to compare the IgA S.I. in the strain (English specification, page 40, lines 9 to 19). The measurement results are shown in Table 1 below.

[Table 1]

Table 1: IgA production enhancing activity of 60 strains, using a Peyer's patch cell culture system

| Strain No. | <u>Genus</u> | Species | IgA S.I. |
|-------------|------------------------|------------------|----------|
| | Control (PBS) | | 1.00 |
| | Positive Control (LPS) | | 7.42 |
| ONRIC b0239 | <i>Lactobacillus</i> | <i>plantarum</i> | 5.61 |
| ONRIC b0240 | <i>Lactobacillus</i> | <i>plantarum</i> | 6.31 |
| ONC141 | <i>Lactobacillus</i> | <i>plantarum</i> | 1.7 |

Table 1 shows that the only strains having an IgA S.I. value of 5 or more are *Lactobacillus plantarum* ONRIC b0239 and b0240, which are both the lactic acid bacteria of the present invention. In contrast, *Lactobacillus plantarum* ONC141 merely has an IgA S.I. value of 1.7.

As described above, the IgA production-enhancing activity of *Lactobacillus plantarum* ONRIC b0239 and b0240, which are both lactic acid bacteria of the present invention, is clearly higher than that of *Lactobacillus plantarum* ONC141.

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I, undersigned, declare that all statements made herein of my own knowledge

are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 20/10/2009

Satoko Yamahira
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